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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,329	09/25/2003	Joaquin Blaya	0050.2061-000	5686

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EXAMINER

FLORY, CHRISTOPHER A

ART UNIT	PAPER NUMBER
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3762

MAIL DATE	DELIVERY MODE
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02/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<i>Office Action Summary</i>	Application No.	Applicant(s)	
	10/671,329	HERR ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER A. FLORY	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2008.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 October 2008 has been entered.

Response to Arguments

2. Applicant's arguments with respect to claims 1-36 have been considered but are moot in view of the new ground(s) of rejection and a new interpretation of the previously applied references given the amended claim language.

3. It is noted that Applicant has amended claims 1, 12, 19, 25 and 31 to read such that the device modulates "in an updating manner at least twice during each walking cycle." Upon further examination of the applied references, it is considered a reasonable interpretation that each of the references operates in a locking/unlocking fashion as has been previously discussed. Such a method qualifies as updating at least twice per cycle, since the device first pulls or locks the foot in an upwardly flexed position in late stance or early swing, and then releases the locking mechanism on heel strike to satisfy the criterion of updating a second time during the same cycle.

Regarding new claims 37-41, it is also noted that that these devices and methods are

considered to read on the language of a modulation that is adaptive in nature, since information from each gait cycle is inherently used in modulating the device function.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 19-23 and 32 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 19 merely recites a method of modulating joint stiffness or damping of an ankle joint in an updating manner at least twice during each walking cycle. This is effectively claiming the natural process of walking itself under normal physiological conditions, since tensing of the muscles in the leg provides the claimed modulation of joint stiffness and damping, and is updated in a constant manner throughout gait and over time as the muscles fatigue. Claims 20-23 and 32 effectively also claim the natural process of walking as they relate to specific stages of the gait cycle.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 4, 10, 11, 19, 20, 22, 29, 30, 37 and 39 stand rejected under 35 U.S.C. 102(b) as being anticipated by Beard et al. (US Patent 5,112,296, hereinafter Beard'296).

Regarding claims 1, 4, 10 and 37, Beard'296 discloses a variable-impedance active ankle foot orthosis (title; abstract; column 3, lines 5-40; column 4, lines 20-25; column 5, lines 50-60) comprising an actuator coupled to a foot portion of the orthosis (Fig. 1, actuator 10; column 4, lines 1-5 and 25-30; column 5, lines 1-48) for modulating a joint stiffness or damping of an ankle joint at least twice during each walking cycle for treating an ankle foot gait pathology, wherein the pathology comprises drop foot (abstract; column 5, lines 38-60). It is noted that there is inherently a joint formed between the leg portion 4 and foot portion 2. Alternatively, the knee orthotic joint 8 can also be considered to anticipate the claims as written, since it is not specified that the joint be the ankle joint, but rather that the joint be related to treatment of an ankle foot gait pathology.

Regarding claim 2, Beard'296 discloses a torsional spring stiffness control and spring-damper positional control (Fig. 6; column 5, lines 1-48). It is also noted that the actuator controls the stiffness of the knee orthotic joint.

Regarding claim 11, a drop foot patient inherently has one or both of anterior or posterior muscle weakness. Therefore, the Beard'296 device inherently treats a patient having such conditions.

Regarding claims 19, 20, 22 and 39, Beard'296 discloses a method of modulating joint stiffness or damping of an ankle joint of an orthosis at least twice during each walking cycle (abstract) wherein the method includes adjusting the stiffness of the joint during controlled plantar flexion and minimizing impedance during late stance (column 1, lines 20-36; column 2, lines 10-67; column 5, lines 47-60). It is noted that the joint between the leg portion and foot portion inherently exists and is inherently modulated throughout gait. It is also noted that the impedance of the knee orthotic joint is modulated throughout the walking cycle, and therefore anticipated the claims.

Regarding claims 29 and 30, the spring disclosed in Beard et al is considered to be operatively coupled to the orthotic joint both at the ankle and to the knee orthotic joint (4). Beard'296 also discloses sensing one or more parameters of the orthotic joint (column 4, lines 60-68)

5. Claims 24 and 33-36 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Stein (US Patent 5,643,332, hereinafter referred to as Stein'332).

Stein'332 clearly outlines a FES stimulation device and method which modulates ankle stiffness during the swing phase of a walking cycle, which inherently provides control during controlled plantar flexion and minimizes forefoot collision. Regarding the newly submitted claim limitation of modulation during swing phase, reference is specifically made to column 6, lines 34-55.

6. Claims 24 and 33-36 stand rejected under 35 U.S.C. 102(e) as being clearly anticipated by Swain et al. (US Patent 6,507,757).

Regarding claim 24 Swain et al. clearly discloses the invention as claimed (Figs. 1-6; abstract; column 2, lines 16-67; column 12, line 10 through column 14, line 10).

Regarding the newly submitted claim limitation of modulation during swing phase, reference is specifically made to column 1, lines 16-37; column 12, lines 27-43; and column 13, lines 3-50.

7. Claims 1-9, 11-23, 25-29, 32 and 37-40 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Johnson et al. (US 5,662,693, hereinafter Johnson'693).

Particular emphasis is placed on the abstract; Figures 1, 3c, 5 and 9; column 8, lines 4-14; column 9, lines 3-27; column 10, lines 55-65.

Specifically regarding claim 5, the actuator shown in Figure 3c of Johnson'693 can be considered a series elastic actuator.

8. Claims 1-4, 6-8, 11-23, 25-30, 32 and 37-40 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Horst (US 6,966,882, hereinafter Horst'882).

Particular emphasis is given to the abstract, Figures 1 and 4-6 and related paragraphs, particularly as pertains to assist, monitor, and rehabilitate modes 508-512 to address the adaptive nature of the modulation.

9. Claims 31 and 41 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Goffer (US 2003/0093021, hereinafter Goffer'021).

Emphasis is placed on paragraphs [3], [6], [220], [221], [225] and [226] which describe a method of treating an ankle foot gait pathology using functional electrical stimulation in conjunction with a traditional orthosis or brace.

10. Claims 1-5, 10-15, 26-28, 37 and 38 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Grim (Re. 34,661, hereinafter Grim'661).

Grim'661 is considered to clearly disclose the invention in the abstract; column 2, lines 15-31; and Figures 1 and 2 with related paragraphs. Regarding the limitation of the modulation being adaptive during the walking cycle, it is noted that the natural stiffness of the boot portion provides spring-like control of ankle flexion and thereby joint stiffness based on the positioning of the foot and bending of the shoe according to that angle. Additionally, the disclosed high viscosity gel bladder acts as a spring that dampens the movement of the joint and is more resistive to sudden movements than gradual movements as disclosed. Further, as the gel warms due to prolonged wear and use, the resistive properties will change accordingly and is thus considered a further example of an adaptive modulation over the walking cycle.

11. Claims 1-3, 12, 26-28, 37 and 38 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kelly et al (US 5,898,948, hereinafter Kelly'948).

Kelly'948 generally discloses a sock/support structure made of an elastomeric material to support the ankle, foot and lower leg (title, abstract). It is recognized that this can reasonably be interpreted as damping the ankle joint by providing compression/relaxation to the natural musculature of the ankle during the walk cycle. Further, the elastomeric materials disclosed can reasonably be interpreted as a spring actuator.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 6-8 stand rejected under 35 U.S.C. 102(b) as anticipated by Beard'296 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Beard'296

Regarding claims 6 and 8, Beard'296 discloses an angle sensor (Fig. 4, radial resistor 24; column 4, lines 60-68; column 6, lines 18-36) capable of being used on the ankle. Furthermore, since a knee angle inherently has a correlated and consistent ankle angle during the standing phase, measuring the angle of the knee is synonymous with measuring the correlated ankle angle.

In the alternative, angle sensors are well known in the art, such as those described in Beard'296, Stein'332 and Horst (US Patent 6,966,882, hereinafter referred to as Horst'882), all of which are capable of being used on the ankle of a patient suffering drop foot. Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Beard'296 device to monitor the ankle rather than the knee, because the knee angle is an equivalent measurement to the ankle angle in the control sense as discussed above.

Regarding claims 7 and 8, Beard'296 discloses EMG sensors which function as ground reaction force sensors (column 4, lines 50-60; column 5, line 59 through column 6, line 18). At foot strike, the musculature of the leg intuitively reacts to the impact by

increasing stimulation to the leg stabilizer muscles in order to absorb the force of the impact and balance the patient while walking. Thus, impact ground force is transferred quantifiably to contractions of the leg musculature that is being sensed by the EMG electrodes of the Beard'296 device.

In the alternative, ground reaction force sensors (or foot switches) are well known in the foot orthosis art and are described in Horst'882, Swain et al., and Naft et al. (US Patent 6,517,503). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Beard'296 with a ground reaction force sensor as described in the prior art cited above to provide the Beard'296 system with an accurate means of distinguishing the varying stages of the walking cycle to more accurately time activation of the orthosis to prevent the symptoms of drop foot.

14. Claim 9 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Beard'296 in view of Swain et al. or in view of Naft et al. (US Patent 6,517,503).

Regarding claim 9, Beard'296 discloses the invention substantially as claimed but does not expressly disclose a foot switch. In the same field of endeavor, Swain et al. teaches the use of a foot switch for sensing foot rise or foot strike in order to accurately deliver stimulation for treatment of drop foot (abstract). Additionally in the same field of endeavor, Naft et al. teaches use of a foot switch in an external orthosis device to selectively lock and unlock the knee joint in order to provide improved gait (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Beard'296 with the foot switch of either Swain et al. or Naft et al. to provide the Beard'296 system with the same advantage of

improving patient gait and treating drop foot (motivation to combine provided by the abstracts of Swain et al. and Naft et al.).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Christopher A. Flory/
25 February 2009

/George Manuel/
Primary Examiner